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Pandemic profiteers?: Publicly funded Vanderbilt University aims to make the COVID-19 disaster its financial windfall

Edward Hammond

Vanderbilt University is in hot pursuit of pandemic profits. Antibodies from Vanderbilt, potential COVID-19 treatments whose discovery was paid for by the public, have been turned into private property as the University and its partner, the drug giant AstraZeneca, position themselves to reap profits from the sale of expensive monoclonal antibody (MAB) drugs.

The privatization of decades of publicly funded antibody research is a particularly depressing spectacle in the face of the global misery caused by COVID-19. In the face of the disaster, many might think that non-profit researchers who depend on public grants for financial support would be eager for their discoveries to be put to maximum social benefit. After all, if the researchers' COVID-19 work, as well as the development of their lab's capabilities, has been paid for with a reliable stream of public money that dates back decades, shouldn't the lab's discoveries be available to the public at a minimal price?

No superior testament to the societal value of public funding for biomedical research could exist than for the benefits of research richly funded by the public to be equitably delivered to all people at a time of global crisis.

Unfortunately, such thinking does not prevail at Vanderbilt, a private, non-profit university in Nashville, Tennessee (US), that is noted for its biomedical research.

Vanderbilt's institutional goals, at least as far as its COVID-19 antibodies are concerned, appear to be maximizing its own profits. Taking a highly proprietary approach to its COVID-19 treatment ideas, Vanderbilt is rushing to lay proprietary claims. In one notably callous publication, it even publicly congratulated itself over the frenetic pace of its applications for COVID-19 patents, licences to which the University is peddling to pharmaceutical companies.

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Address: 131 Jalan Macalister, 10400 Penang, MALAYSIA **Tel:** 60-4-2266728/2266159 **Fax:** 60-4-2264505
Email: twn@twnetwork.org **Website:** www.twn.my

Vanderbilt's vaccine centre and a spigot of public dollars

With decades of funding from the US National Institutes of Health and Department of Defense, the Vanderbilt Vaccine Research Center has developed expertise in quickly isolating potentially useful antibodies in samples taken from infectious disease victims. This speciality is useful in developing vaccines but also in diagnostic tests and as monoclonal antibody drugs, which is where Vanderbilt's COVID-19 antibodies appear to be primarily being used.[1]

MABs can be used to treat cases of COVID-19 infection, and even as a sort of short-term vaccine (e.g., for healthcare workers). MABs are likely to be the first drugs that come on the market that are specifically designed to treat COVID-19.

Vanderbilt's Vaccine Research Center, and its leadership, have relied on decades of public money[2] to develop the Center's antibody isolation capabilities. Going back to the 1990s, it received over $100,000 a year from the US health ministry to isolate respiratory syncytial virus (RSV) antibodies. This was cranked up to $400,000 a year in the early 2000s and then supplemented by another annual $400,000 to work on fast ways to sort and exploit immune cells. In the early 2000s, an additional $150-200,000 a year came in to specifically look at vaccinia virus antibodies.

In 2004, US taxpayers gave Vanderbilt $500,000 to install specialized cell sorting and processing equipment. At the same time, the Center's vaccinia antibody funding was bumped up to between $300,000 and $450,000 per year. Also in 2004, a new project on rotavirus antibodies came online. That one was worth $377,000 a year. In 2005, a new project on metapneumovirus (MPV) came in with additional funding averaging another $325,000 a year.

While the vaccinia project ended – temporarily – with a $285,000 grant in 2006, Vanderbilt's Vaccine Research Center marched through the mid-2000s collecting government cheques to support its facilities and for the previously mentioned RSV, MPV and rotavirus research.

An AIDS antibody project attracted funding beginning in 2008 with a $620,000 annual grant, later upped to $882,000, and the Vaccine Research Center entered the 2010s with RSV, HIV and rotavirus antibody public funding from the US health ministry.

By 2010, the six-year-old cell sorting machine installed in 2004 was considered outdated, so the US health ministry paid another $500,000 for a new "Becton Dickinson custom multilaser LSRII flow cytometer".

The AIDS antibody work eventually ended, but it was quickly replaced by other public funds. A grant worth over $300,000 a year on dengue antibodies came in 2011 and, in the same year, on the heels of the 2009/10 H1N1 influenza pandemic, Vanderbilt struck gold with nearly $1.1 million per year to isolate influenza (and vaccinia) antibodies. In 2012, this was bumped up to $1.7 million. A separate new project also on influenza added $400,000 more.

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1 Monoclonal antibodies (MABs) that directly target COVID-19 are akin to a refinement of convalescent plasma therapy, the treatment wherein a recovered patient's blood plasma is transfused to a current victim in the hopes that antibodies from the recovered person will help the current victim fight off the disease. In the case of MAB drugs, rather than the untargeted approach of transferring whole plasma, which has thousands of components, a single antibody is produced (in steel or plastic containers by biotech means) and administered as a drug. The single antibody, which is sometimes used with one or more others in a MAB "cocktail", has been selected as being one that is (hopefully) especially effective against the disease. These single antibodies, cocktails, and ways to formulate and administer them are typically covered by patents and other intellectual property (e.g., manufacturing trade secrets).

2 All of the funding figures in this section are drawn from a multiyear search for grants with James Crowe (Director of the Vaccine Research Center) as an investigator on NIH Reporter, the US National Institutes of Health funding reporting system, available at https://projectreporter.nih.gov/reporter.cfm

In 2013 and 2014, an additional over $200,000 a year came to isolate rift valley fever virus antibodies. The icing on the cake was a separate public grant to pay $100-200,000 a year for PhD students to work at the Center, and another grant to pay administrative expenses related to Vanderbilt's coordination with other labs.

2016 was an even better year for public money inflows. The Center first brought in a $2.4 million annual grant for "structure based design of antibodies and vaccines." Then came $700,000 to isolate chikungunya virus antibodies and, with the Ebola outbreak in West Africa, more money to look for filovirus antibodies.

In 2017, a new $2.6 million for influenza antibodies came along (reduced to $1.3 million in 2018) as well as additional funding to coordinate with other labs funded by the US biodefence programme.

By the late 2010s, Vanderbilt's centre soldiered on with public funds to study zika, influenza and chikungunya antibodies, along with core support for its facilities and coordination with other biodefence researchers. All of these grants, and the ones before, are public money given to Vanderbilt in order for it to develop its abilities to isolate and characterize infectious disease antibodies.

And that's just the health ministry funding. In ways that are much harder to document, the US Department of Defense has also supported the Vaccine Research Center, particularly DARPA, the US Defense Advanced Research Projects Agency.

Along comes COVID-19

The most important US defence ministry grant to Vanderbilt, for this COVID-19 story, came in January 2018, when DARPA signed a five-year agreement with Vanderbilt that is "worth up to $28 million." The rather ambitious goal of the project, called the "Pandemic Protection Platform" programme,[3] is "to develop protective antibody treatments that can be rushed to healthcare providers around the world within 60 days after the outbreak of viral disease."

When COVID-19 came a little over two years later, it was Vanderbilt's moment of truth. The emerging pandemic was precisely the scenario that DARPA was paying Vanderbilt to prepare for.

Vanderbilt did indeed rush to healthcare providers in early 2020, but it was not bringing antibody treatments. Rather, Vanderbilt was in a hurry to get tissue samples of COVID-19 victims, both because of the public health emergency and because it wanted to patent antibodies isolated from the samples before other research groups did.

One healthcare provider Vanderbilt tapped was the University of Nebraska, where a publicly funded national hospital quarantine ward,[4] specializing in treatment of unusual viruses, was among the first US hospitals to treat COVID-19 patients in February 2020. The first COVID-19 patient samples that Nebraska sent under a material transfer agreement (MTA) to anyone else were on 2 March. That shipment was to Vanderbilt.[5] [6] The

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3 Confusingly, there are at least three different names used for this programme. Vanderbilt refers to it as the "Pandemic Protection Platform", whereas AstraZeneca calls it the "Pandemic Preparedness Platform". DARPA itself refers to the effort as the "Pandemic Prevention Platform".

4 See: https://www.unmc.edu/healthsecurity/education/capabilities/index.html

5 University of Nebraska MTA with Vanderbilt University, 2 March 2020. Variously noted with document numbers MTS3255 and MTA20247T. Obtained under the Nebraska Public Records Law.

6 Four days later, on 6 March, Nebraska transferred COVID-19 patient samples to Mt. Sinai School of Medicine in New York, another university playing at the game of turning the pandemic into a commercial success. Notably, that MTA too establishes that Mt. Sinai's collection of samples was under DARPA funding, through a programme called ECHO (Epigenetic Characterization and Observation).

Vanderbilt-Nebraska MTA specifically states that Vanderbilt work with the samples is under the DARPA Pandemic Protection Platform programme.[7]

Once Vanderbilt acquired the samples from Nebraska and other healthcare providers, it used its skills and equipment – the fruit of decades of heavy public investment – to look for SARS-CoV-2 antibodies. Unsurprisingly, Vanderbilt did isolate antibodies that it and others believe may be effective in treating the pandemic disease.

Did Vanderbilt then rush to healthcare providers, or public agencies, around the world with those publicly funded potential treatments, as Vanderbilt described the DARPA programme? Did it offer the antibodies to the US government, which had paid for their discovery both directly and through decades of investment in developing Vanderbilt's capabilities? Did Vanderbilt analyze how its publicly funded antibodies might be produced through a public effort, to avoid high prices and intellectual property problems?

None of those possibilities seems to have been the case.

What Vanderbilt did do was rush to file patent applications. A University article unashamedly crows about the "record breaking" speed at which Vanderbilt has been laying claim to antibodies and other COVID-related discoveries, proudly noting "the filing of 11 patent applications in record time."[8] Success, for Vanderbilt, seems to be defined as rapid privatization of publicly funded discoveries that might help stop the pandemic.

Patent applications filed, Vanderbilt began peddling its antibodies to pharmaceutical multinationals and diagnostics companies. It found success. In April, Vanderbilt quickly signed an evaluation deal and then, in June, an exclusive licence for six antibodies to AstraZeneca, which will develop two of them as the company's lead MAB cocktail drug.

Vanderbilt also licensed antibodies to Leinco Technologies, a maker of test kits and test kit ingredients. Finally, in a bit of self-dealing that is common at US research universities, it licensed other antibodies to a company named IDBiologics. It turns out that IDBiologics is a project of none other than James Crowe, the Director of the Vanderbilt Vaccine Research Center.[9]

The terms of Vanderbilt's licences are confidential, but the University has said nothing to suggest that the deals were executed with anything less than Vanderbilt's best efforts to maximize its financial benefits.

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7 The author has sought additional early material transfer agreements for SARS-CoV-2 viruses and encountered stiff resistance from US public universities that want to keep their transfers of the virus a secret. The major US coronavirus research centre at the University of North Carolina at Chapel Hill has denied access to all of its SARS-CoV-2 MTAs in their entirety, arguing that every bit of every MTA it has signed for COVID materials must be kept secret from the public because of the potential commercial value of research in progress. The University of Georgia answered a request for its SARS-CoV-2 MTAs by claiming that it is unable to find its own CoV-2 MTAs without manually reviewing every MTA executed across the entire university, including by unrelated programmes like plant breeding and soil science, for the entire relevant time period. This grossly exaggerated and unnecessary review, Georgia insists, will require many hours of professional staff time, and those many hours must be paid for by the freedom of information requester. Of course, in reality, the University does not need to review MTAs from research that has nothing to do with COVID, but by insisting on the elaborate and overcomplicated procedure, it uses exorbitant fees as a way to stop transparency.

8 Vanderbilt Center for Technology Transfer & Commercialization. 2020. Center for Technology Transfer & Commercialization breaks records in rapid facilitation of COVID-19 related agreements. Press release. 9 July. URL: https://news.vanderbilt.edu/2020/07/09/center-for-technology-transfer-commercialization-breaks-records-in-rapid-facilitation-of-covid-19-related-agreements/

9 See http://idbiologics.com/?page_id=385

AstraZeneca and the Pandemic Protection Platform programme

AstraZeneca too is part of the DARPA Pandemic Protection Platform, and the UK-based company has also benefitted from US public research money in relation to the COVID-19 MABs and their development.

Details about DARPA funding, however, are notoriously difficult to pin down and AstraZeneca has not publicly elaborated on its arrangements with the US defence agency. The Pandemic Protection Platform was initiated in 2018 and included AstraZeneca. The Platform was a five-year project, suggesting it will remain active at least until 2023. But despite having licensed the MABs from Vanderbilt, AstraZeneca now refers to its participation in the Pandemic Protection Platform in equivocal, past-tense terms.

At the very least, AstraZeneca's statements downplay the public investment. In relation to COVID-19 MABs generally, the company says that it is "using proprietary antibody discovery technology that was previously developed under an agreement with the US Defense Advanced Research Projects Agency (DARPA) as part of the Pandemic Preparedness Platform programme". This may refer to a "technology investment agreement", whose partial text is publicly available, that AstraZeneca entered into with DARPA in 2018,[10] though that agreement is only part of the story.

To launch trials of the Vanderbilt antibodies, AstraZeneca has received $23.7 million from DARPA and BARDA, the US biodefence agency.[11] AstraZeneca does not itself appear to have made any announcement of this public support. But probably not coincidentally, Vanderbilt issued a press release announcing its antibody licences to AstraZeneca on the same day that BARDA posted information on its website announcing the $23.7 million grant. Like AstraZeneca, Vanderbilt made no explicit reference to new funding from DARPA/BARDA to test the MABs when it announced their licence agreement.

The timing would suggest that the two events – the grant and the licence – are linked, and that either Vanderbilt or, more likely, AstraZeneca made signing the MAB deal contingent on still more money coming from the US government.

Auguring towards inefficiency and more expensive drugs

Vanderbilt's MABs are shaping up to be a case of private hijacking of publicly funded research. And while AstraZeneca has not announced pricing for its candidate, MABs are a notoriously expensive type of drug and AstraZeneca has made no public commitments about prices (assuming the antibodies pass clinical trials). AstraZeneca has also exclusively licensed six antibodies from Vanderbilt yet is only developing two of them, raising questions about the others. Will they be fully evaluated? Is AstraZeneca trying to "catch and kill" the antibodies?

If Vanderbilt's licence to AstraZeneca has any special provisions for the public interest, or to ensure affordability and stimulate production at sufficient scale, the University has not mentioned them. If Vanderbilt officials have suffered any pangs of conscience about their rush to privatize COVID discoveries, they have not expressed as much either. To the contrary, Vanderbilt has released self-congratulatory press items about the speed and breadth of its COVID-19 intellectual property claims,[12] as if attacking the public interest was somehow laudable.

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10 Though marked "Proprietary & Confidential", this contract can be downloaded from AstraZeneca's website at: https://www.astrazeneca.com/content/dam/az/Government%20Contract%20T%26Cs/Flowdown%20Requirements%20for%20Subcontracts.pdf

11 BARDA. 2020. BARDA, DARPA, and AstraZeneca Collaborate to Develop a Novel COVID-19 Therapeutic. Press release. 9 June. https://www.medicalcountermeasures.gov/newsroom/2020/astrazeneca/

12 Vanderbilt Center for Technology Transfer & Commercialization, op. cit.

Plainly, Vanderbilt's profit seeking and lower drug prices stand in direct opposition. The University has already been paid by the government. As the patent rights holder, it might have leveraged its power in the public interest, but it does not appear to have done so. It instead appears as if the University counts collecting profits for itself as being equally or more virtuous than using its position to work for affordable delivery of publicly funded drug discoveries to COVID-19 victims.

The US government too has potential leverage over the Vanderbilt MABs due to the funding that it has provided both Vanderbilt and AstraZeneca. AstraZeneca's technology investment agreement with DARPA (and perhaps other agreements) contains government "march-in rights",[13] and DARPA's contracts with Vanderbilt may well also contain them. This leverage might be used in the public interest; however, the entwining of government and industrial interests in the US has made it quite rare for the US government to assert its interests in pharmaceutical inventions. With the nationalistic approach to COVID-19 taken by the Trump administration, in the unlikely event that the US were to exert its patent powers at all, at present any such action would likely be for the benefit of the United States.

With billions of dollars of government investment – globally – flowing into COVID-19 vaccines and therapies, what might have instead happened with Vanderbilt's antibodies is disheartening to contemplate. Rather than a licence that places production and pricing decisions exclusively in AstraZeneca's hands, making the antibodies and the cell culture inputs necessary to produce them available on a non-exclusive basis to many manufacturers would not cost the public significantly more than what it is already paying. After all, the US is already paying for testing and development – so why not make the benefits of that investment more broadly available? And if the antibodies are effective, this would stimulate lower-cost production in more countries.

Which of the many COVID-19 MAB drugs under development proves to be most effective remains to be seen. Each company advancing its own candidate(s) without direct comparison at early stages is the present, inefficient approach. If the Vanderbilt antibodies emerge from presently ongoing trials as being particularly effective, the course of action that the University has taken in licensing them exclusively to AstraZeneca will likely result in more expensive treatments and, quite possibly, lower availability.

Edward Hammond *directs Prickly Research (www.pricklyresearch.com), a research and writing consultancy based in Austin, Texas, USA. He has worked on biodiversity and infectious disease issues since 1994. From 1999 to 2008, Hammond directed the Sunshine Project, an international non-governmental organization specializing in biological weapons control. Hammond was Programme Officer for the Rural Advancement Foundation International (now the ETC Group) from 1995 to 1999. He holds MS and MA degrees from the University of Texas at Austin, where he was an Inter-American Foundation Masters Fellow.*

For previous Intellectual Property and COVID-19 Vaccines Series postings, please see: https://twn.my/title2/briefing_papers/covid19_vaccines_series.htm

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[13] The Bayh-Dole Act of 1980 awards title to inventions made with US federal government support, allowing patent claims over inventions by recipients of public funding. It also provides federal agencies with "march-in rights" that allow the government, in specified circumstances, to require the contractor or successors in title to the patent to grant a "nonexclusive, partially exclusive, or exclusive license" to a "responsible applicant or applicants." If the patent owner refuses to do so, the government may grant the licence itself. This is a form of compulsory licensing, a feature of patent law.